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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,020	09/18/2006	Frederic Ben	58767.000017	3183
21967 7590 03/16/2010 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109				
EXAMINER				
LSTVOYB, GREGORY				
ART UNIT		PAPER NUMBER		
1796				
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03/16/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,020

Applicant(s)

BEN ET AL.

Examiner

GREGORY LISTVOYB

Art Unit

1796

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 18-27 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 18-27 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 18-27 and new claim 33 rejected under 35 U.S.C. 103(a) as being unpatentable over Gruber et al (US 6355772) in view of Bowman (US 3047524) (cited in the previous Office Action) as evidences by Nevin et al (US 4273920).

Gruber teaches a catalytic system, which contains a strongly acidic ion-exchange polymeric catalyst Amberlist 36 (see Example 8, Column 20, line 55, meeting the relevant limitations of claims 16 and 19-21).

In addition, Gruber teaches an alcohol as a part of reaction mixture (see Column 15, line 5), which used for molecular weight control, meeting the relevant limitations of claims 22-26.

Gruber does not teach both components in one catalytic system.

The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) , 325 U.S. at 335, 65 USPQ at 301, see also also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) and MPEP 2144.07.

Therefore, it would have been obvious to a person of ordinary skills in the art to use Amberlist 36 and alcohol together in one catalytic system. The above compounds fulfill different functions of catalyzing polymerization and regulating its molecular weight.

Gruber does not teach the nature and amount of alcohol used.

Bowman teaches a polymerization of glycolic acid, which is analogous to polymerization of lactic acid disclosed by Gruber.

Bowman teaches an addition of 1-5 mol percent (see Column 2, line 10) of a monohydric aliphatic alcohol , such as methanol, ethanol or hexanol (see Column 1, line

40) or, in general, aliphatic alcohol containing 1-6 carbon atoms (see Column 1, line 40) in order to produce a polymer with desired properties.

Regarding the newly added limitation claiming "the quantity of the one or more lactide and/or glycolide monomer(s), relative to the quantity of (co)oligomerization additive ranges from 2 to 30 molar equivalents", Gruber teaches that the amount of molecular weight control agent should be sufficient to control a molecular weight within the range of 10000 to 300000 (see Column 15, line 10).

As evidences by Nevin the process for synthesis of lactic-glycolic copolymer in melt and solution at the presence of acidic ion-exchange resin produces a polymer with Molecular weight within the range of 6000-35000. (see Abstract).

It has long been an axiom of United States patent law that it is not inventive to discover the optimum or workable ranges of result-effective variables by routine experimentation. In re Peterson, 315 F.3d 1325, 1330 (Fed. Cir. 2003) ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Boesch, 617 F.2d 272,276 (CCPA 1980) ("[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art."); In re Aller, 220 F.2d 454,456 (CCPA 1955) ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.").

"Only if the 'results of optimizing a variable' are 'unexpectedly good' can a patent be obtained for the claimed critical range." In re Geisler, 116 F.3d 1465, 1470 (Fed. Cir. 1997)(quoting In reAntonie, 559 F.2d 618, 620 (CCPA 1977)).

Therefore, it would have been obvious to a person of ordinary skills in the art to add 1-5 mol percent of aliphatic alcohol containing 1-6 carbon atoms to Gruber's system at the suitable amount in order to obtain a polymer with desired properties (i.e. required molecular weight).

Regarding newly added claim 33, both Gruber and Nevin disclose a systems free of metal catalyst (see Example 8 of Gruber and Abstract of Nevin).

Response to Arguments

Applicant's arguments filed 2/24/2010 have been fully considered but they are not persuasive.

Applicant argues that since polymer in Gruber's application has a low molecular weight, when produced with ion-exchange resin, the molecular weight control agent is not needed.

However, polylactide polymer, produced with acidic ion-exchange resin may have broad range of molecular weights. In fact, newly added reference (Nevin) teaches

the process takes place at the presence of acidic ion-exchange resin, where the polymer has molecular weight within the range of 600-35000.

Applicant submits that Gruber does not teach newly claimed amount of molecular weight control agent.

However, Gruber suggests that the amount of molecular weight control agent should be sufficient to control a molecular weight within the range of 10000 to 300000 (see Column 15, line 10). This amount is dictated by aimed molecular weight and can be determined in the course of routine experimentation (see discussion above).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY LISTVOYB whose telephone number is (571)272-6105. The examiner can normally be reached on 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GL
/GREGORY LISTVOYB/
Examiner, Art Unit 1796